UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert R. Kugler, District Court Judge Oral Argument Requested
This Document Relates to All Actions	

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO PRECLUDE OPINIONS OF DEFENSE EXPERT STEVEN W. BAERTSCHI, PH.D.

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Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis Pharma, Inc., and Actavis LLC (collectively, "Teva") submit this memorandum of law in opposition to Plaintiffs' Motion to Preclude Opinions of Defense Expert Steven W. Baertschi, Ph.D. [ECF No. 2289] ("Motion") and state as follows:

INTRODUCTION

Analytical and organic chemist Dr. Steven Baertschi, Ph.D. was retained by Teva to assess Teva's compliance with industry standards related to the testing and analysis of its incoming valsartan active pharmaceutical ingredient ("API") and the manufacturing of its finished dose valsartan products. Dr. Baertschi worked for more than 25 years in pharmaceutical development at Eli Lilly Company, including working on more than 15 New Drug Applications, specifically sections on degradation-related impurities and stability-indicating analytical methods. He is a fellow of the American Association of Pharmaceutical Sciences for his contributions to the advancement of pharmaceutical sciences in degradation chemistry and analytical methodologies for impurities, was a member of the PhRMA Limited Duration Key Initiative Team (LDKIT) for Genotoxic/Mutagenic Impurities, ICH M7 Guidance; past co-chair of the ICH M7 Degradants Subtopic Group LDKIT; and past member of the ICH M7 Quality Subgroup LDKIT and USP Expert Panel on Impurities, among other achievements.

Based on his extensive background and expertise in pharmaceutical industry standards and his review and analysis of voluminous corporate documents, industry guidances, scientific literature, and other materials, Dr. Baertschi opines that:

- Analyzing low-level impurities such as the NDMA and NDEA found in the valsartan medication is extremely difficult and requires specialized equipment, analytical testing methods, and expertise.

- Drug manufacturers do not and cannot test for every conceivable impurity, and it is particularly difficult to detect and quantify impurities at such low levels as the NDMA / NDEA impurities found in valsartan.

- The specification testing for valsartan medication in place prior to July 2018 did not include testing capable of detecting NDMA and NDEA at the levels at issue. The levels of all unknown impurities in valsartan medications, including the NDMA and NDEA impurities that were discovered, were within the limits of the specifications approved by the FDA for unknown impurities at all times that Teva's valsartan-containing medications were available to patients, and Teva's valsartan was therefore the "same" as the RLD.

- Teva acted as a reasonably prudent and careful manufacturer in making, inspecting, and testing its finished valsartan products in connection with the process change implemented for ZHP API in 2014 and 2015.

- Teva acted as a reasonably prudent and careful manufacturer in inspecting and testing incoming valsartan API, including performing all testing required by the USP Monograph and ANDA, as well as all testing required and contemplated by genotoxic / mutagenic impurity guidances including ICH M7, and performing appropriate evaluation and testing of residual solvents. It was reasonable and appropriate for a finished dose manufacturer like Teva not to perform further analysis of unidentified peaks of the size seen on Teva's chromatograms of valsartan API batches that were ultimately determined to be NDMA / NDEA.

Expert Report of Steven W. Baertschi, Ph.D. (December 19, 2022) (Exhibit A to Plaintiffs' Motion) ("Baertschi Report") ¶¶ 12-16. Not surprisingly, in the face of Dr. Baertschi's unassailable expertise in the subjects at the heart of this litigation, Plaintiffs have not challenged either his qualifications to render his opinions or their helpfulness to the trier of fact.

Instead, Plaintiffs' Motion largely boils down to a critique of Dr. Baertschi's methodology based only on Plaintiffs' counsel's say-so about what he should have considered and even the breadth of his opinions. Plaintiffs repeatedly argue—citing no legal or scientific support—that Dr. Baertschi should have opined on additional topics, including ZHP's conduct and Teva's regulatory compliance, characterizing his proper cabining of his opinions to the scope of his report and expertise as a failure to consider "contradictory" facts or data. *See, e.g.*, Motion at 10. They also offer their own unsupported opinions about the relevant industry standards and complain that Dr. Baertschi relied on different ones, ignoring his explanations for why he relied on the standards he did and why the standards Plaintiffs point to are inapplicable. *See, e.g., id.* at 17-18. Even setting aside that much of the supposed "contradictory" evidence is beyond the scope of Dr. Baertschi's opinions, this Court has specifically rejected Plaintiffs' arguments as a basis for exclusion of an expert's opinions. *See e.g.*, Transcript of March 2, 2022, Evidentiary Hearing ("Evidentiary Hearing") 148:8-17 ("This is a complaint that both sides have as to every single

expert in this case. And this is about the cherry picking of the data. But really that's what experts do. They look at the data, they decide and they express their reasons why some data is more important at arriving at their opinions than others. So long as they explain how they come to their opinions, and so long as they attempt to explain why they didn't think contrary data is not relevant to their opinion, then that's not objectionable."). And Plaintiffs cite no law supporting their argument that Dr. Baertschi was required to consider Teva's compliance with regulations and standards outside the scope of his expertise to form reliable opinions related to organic and process chemistry and pharmaceutical development. Notably, Plaintiffs' own organic chemistry expert Dr. Stephen Hecht opines on similar issues despite having no experience with pharmaceutical industry regulations, or experience in the pharmaceutical industry whatsoever.

Plaintiffs' challenge to Dr. Baertschi's methodology is baseless, and the Court should deny their Motion.

FACTUAL BACKGROUND

Plaintiffs' Motion begins with a skewed, argumentative "Statement of Facts"—many of which are not "facts" at all and in any case are irrelevant to whether Dr. Baertschi employed a reliable methodology. Plaintiffs first assert that "Teva was aware as early as 2014 that API suppliers frequently misrepresent in their DMFs that the API contains no genotoxic impurities, and that when Teva does an inspection of

the API supplier it learns that genotoxic impurities are present," citing a single Actavis email, which, Dr. Baertschi testified, reflects just one person's belief and provides no information about how widespread this belief was within Actavis, and which he characterized as "anecdotal and speculative." Motion at 2; *see* Deposition of Steven W. Baertschi, Ph.D. (January 26, 2023) (Exhibit B to Motion) ("Baertschi Dep.") 209:6-24. Plaintiffs then assert, based on this single statement from a single employee, that Teva, as a company, "used a method described in a 2006 article by Muller entitled 'A rationale for determining, testing, and controlling specific impurities in pharmaceuticals that possess potential for genotoxicity' to identify potential genotoxic impurities in API." Motion at 2. But Dr. Baertschi explained that the method described in the Muller article does not apply to identifying ***potential***, unexpected impurities—such as the NDMA and NDEA later discovered in valsartan—but to identifying whether an impurity might be genotoxic ***once the impurity is known***. *See* Baertschi Dep. 207:4-209:4.

Plaintiffs next discuss June 2015 and May 2018 Teva audits of ZHP facilities and note these audits are not discussed in Dr. Baertschi's report. *See* Motion at 3. But, as Dr. Baertschi testified, he is not opining on Teva's regulatory compliance, nor on the conduct of ZHP, nor on cGMPs related to Teva's use of ZHP as an API supplier. *See* Baertschi Dep. 203:6-11.

Plaintiffs then assert as fact that Teva expected its API manufacturers "to take a wide range of appropriate steps," including investigating unknown peaks in chromatogram tests. Motion at 4. But Dr. Baertschi testified that manufacturers do not and cannot structurally characterize all unknown peaks. *See* Baertschi Dep. 251:14-252:1. He also opined that the unknown peaks on ZHP's chromatograms were "so low that it would not have stood out as unknown to . . . flag and to investigate." *See, e.g.*, *id*. at 139:18-20; 241:16-242:21; *see also* Baertschi Report ¶ 13. This opinion is shared by Plaintiffs' experts. *See, e.g.,* Deposition of Stephen S. Hecht, Ph.D. (Jan. 13, 2023) ("Hecht Dep.") 129:17-130:14 (excerpts attached to the accompanying Certification of Victoria Davis Lockard, Esq. as Exhibit A).

Next, Plaintiffs declare that Dr. Baertschi's report does not address the fact that ZHP stipulated that its "risk assessment did not specifically evaluate whether [dimethylformamide] was degrading to yield dimethylamine as part of the zinc chloride process…." Motion at 4-5. Dr. Baertschi was not asked to opine on ZHP's conduct. *See* Baertschi Report ¶ 11. In any case, he explained during his deposition that dimethylformamide was generally expected to act as an inert solvent and thus would not have been a focus of a risk assessment associated with a process change. *See* Baertschi Dep. 126:21-127:7, 294:13-18.

Finally, Plaintiffs summarize a November 29, 2018, FDA warning letter to ZHP related to various alleged cGMP deviations and erroneously conclude that

ultimately Teva accepted "ZHP adulterated API." Motion at 5. Again, Dr. Baertschi is clear that he is not opining on the conduct of ZHP, as an API manufacturer, but on Teva's conduct, as a finished dose manufacturer. *See, e.g.*, Baertschi Dep. 220:11-221:5. And, that Teva used "adulterated" API is clearly not a "fact," as Teva's experts dispute this.

In short, Plaintiffs' "Statement of Facts" does not consist of "facts" at all but rather a series of misrepresentations and red herrings, providing no basis for preclusion of Dr. Baertschi's opinions.

LEGAL STANDARDS

Under Rule 702 of the Federal Rules of Evidence, "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education" may offer opinions in a case if (i) "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"; (ii) "the testimony is based on sufficient facts or data"; (iii) "the testimony is the product of reliable principles and methods"; and (iv) "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702. "The inquiry envisioned by Rule 702 is . . . a flexible one," and its focus "must be solely on principles and methodology, not on the conclusions that they generate." *Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579, 594–95 (1993). Rule 702 and *Daubert* "neither require[] nor empower[] trial courts to determine which of several

competing scientific theories has the best provenance. [They] demand[] only that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion." *United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004) (quoting *Ruiz-Troche v. Pepsi Cola Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998)); *see also In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 792–93 (3d Cir. 2017) ("Both an expert's methodology and the application of that methodology must be reviewed for reliability. A court should not, however, usurp the role of the fact-finder; instead, an expert should only be excluded if the flaw is large enough that the expert lacks the 'good grounds' for his or her conclusions.") (internal quotation marks omitted).

ARGUMENT

I. DR. BAERTSCHI EMPLOYED A RELIABLE METHODOLOGY IN RENDERING HIS OPINIONS.

A. Dr. Baertschi employed the same methodology he employs in his scientific work in forming his opinions and considered the evidence relevant to those opinions.

Plaintiffs' Motion begins with a general challenge to Dr. Baertschi's methodology, the crux of which is that he failed to consider "contradictory" evidence because he did not consider and form opinions on issues outside the scope of his expertise and expert report. Plaintiffs cite **no law** supporting the proposition that an expert is required to opine on a particular scope of topics to render his methodology

reliable.[1] To the contrary, courts have repeatedly held that an expert must limit his testimony to the scope of his expertise and his report.[2] *See, e.g.*, *Jackson v. City of Pittsburgh*, Case No. 7-111, 2010 U.S. Dist. LEXIS 82965, at *26-28 (W.D. Pa. Aug. 13, 2010) ("[A] witness may not testify as an expert outside the scope of his or her expertise — the expert's qualifications and skills set the boundaries for that expert's testimony."); *Stokes v. Janosko*, Case No. 2:16-cv-64, 2018 U.S. Dist. LEXIS 113826, at *9 (W.D. Pa. July 10, 2018) ("[T]he purpose of an expert report is to put the other side on notice about the scope of the expert's potential testimony.").

Dr. Baertschi's opines on Teva's compliance with ***pharmaceutical industry standards*** in analyzing and testing its incoming valsartan API and ***manufacturing finished dose valsartan products***—not "the regulatory framework" applicable to Teva, Teva's conduct generally, or the standards applicable to an ***API manufacturer*** like ZHP. Plaintiffs' argument that Dr. Baertschi generally failed to consider evidence "contradicting" his opinions relates primarily to the fact that he does not

[1] Plaintiffs even suggest that Dr. Baertschi was required to include particular words in his report to render his methodology reliable, including charged terms favored by Plaintiffs ("contamination") and words pertaining to topics outside the scope of his opinions ("adulteration" and "recall"). *See* Motion at 1-2. Again, unsurprisingly, they provide no support for this claim.

[2] Indeed, Plaintiffs note the requirement of Rule 26(a)(2) that an expert report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." *See* Motion at 7 (quoting Fed. R. Civ. P. 26(a)(2)(B)(i)).

opine on ZHP's practices, including ZHP's risk assessment and ZHP's compliance with cGMPs. *See* Motion at 10-11. Far from being "central" to Dr. Baertschi's opinions, these topics are outside their scope. *See generally* Baertschi Report. Plaintiffs do not even explain why, in their view, Dr. Baertschi was required to opine on these issues or other topics outside the scope of his report, aside from listing various lines of questioning from his deposition and declaring he should have offered opinions in response to them.[3] *See* Motion at 11–12.

Plaintiffs also contend that Dr. Baertschi did not consider certain "evidence" that he in fact opined on extensively because they do not like his conclusions about those issues, which differ from Plaintiffs' view. For example, they inaccurately claim that Dr. Baertschi did not consider Teva's failure to "predict the possibility of nitrosamine formation despite having knowledge of the route of synthesis used by ZHP to manufacturer [sic] the API, and Teva's lack of testing the ZHP API for genotoxins." Motion at 10. In fact, Dr. Baertschi opines extensively in his report,

[3] For example, Plaintiffs complain that Dr. Baertschi testified that whether Teva was "responsible to patients" (whatever that may mean) for the API in its finished dose products was outside the scope of his opinions. *See* Motion at 12; Baertschi Dep. 222:4-15. They also assert that he would not opine on "whether Teva was responsible for the API" in its finished-dose product," when in fact he asked for that question to be rephrased, as he did not understand it. *See* Motion at 12; Baertschi Dep. 221:17-222:2. Plaintiffs do not explain why Dr. Baertschi was required to offer opinions in response to these vague, confusingly worded questions, on topics outside the scope of his report, in order to reliably opine on Teva's compliance with pharmaceutical industry standards related to its manufacturing and testing of valsartan products. *See* Motion at 11-12.

and testified in his deposition, on Teva's—and the entire industry's—failure to predict the possibility of nitrosamine formation. *See, e.g.*, Baertschi Report at ¶¶ 11, 53; Baertschi Dep. at 126:21-127:7, 150:1-19, 291:11-24, 292:9-293:7. Plaintiffs also incorrectly assert that Dr. Baertschi did not consider "Teva's lack of testing the ZHP API for genotoxins." Motion at 10. Again, Dr. Baertschi does opine on this topic. In his report, he discusses at length the difficulty of testing for unknown, low-level impurities and industry standards for such testing. *See* Baertschi Report ¶¶ 12-13, 15-23. He also testified about Teva's testing of all incoming ZHP API. *See* Baertschi Dep. 134:18-135:11; 306:12-307:13. Based on his knowledge of pharmaceutical industry standards and his consideration of these facts, Dr. Baertschi concludes that "Teva acted as a reasonably prudent and careful manufacturer in inspecting and testing incoming valsartan API." Baertschi Report ¶ 16. Plaintiffs may disagree with this conclusion, but that does not mean that Dr. Baertschi ignored relevant evidence or provide a basis for exclusion of his opinions. *See, e.g.*, Evidentiary Hearing 148:14-17 ("So long as [experts] explain how they come to their opinions, and so long as they attempt to explain why they didn't think contrary data is not relevant to their opinion, then that's not objectionable."); *see also, e.g., Oddi v. Ford Motor Co*., 234 F.3d 136, 145-46 (3d Cir. 2000) ("The test of admissibility is not whether a particular scientific opinion has the best foundation or whether it is demonstrably correct. Rather, the test is whether the 'particular opinion is based on

valid reasoning and reliable methodology. 'The analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination.'") (quoting *Kannankeril v. Terminix Int'l Inc*., 128 F.3d 802, 806 (3d Cir. 1997) (internal citation omitted)).

Setting aside their baseless claims about Dr. Baertschi's so-called failure to consider "contradictory" evidence, Plaintiffs offer no serious challenge to his methodology. The Court can easily discard Plaintiffs' (rather incredible) claim that Dr. Baertschi did not comply with Rule 26(a)(2) because his report states his opinions are based on "scientific methods and procedures" and that "[c]itations to specific reference material are offered in this report where I believe it necessary to cite a specific source. Otherwise, my opinions are derived from a combination of reference sources and my own scientific knowledge." Baertschi Report ¶¶ 1–2. Plaintiffs offer no support for their argument that this "directly conflicts with the requirements of FRCP 26(a)(2)." Motion at 8-9. Dr. Baertschi's report includes an extensive list of his specific source materials, which he testified contains all the materials he considered "[a]s far as I can list them out." Baertschi Dep. 28:19-29:6. Dr. Baertschi could not possibly list everything that has formed his general scientific knowledge, nor is this required under Rule 702. Knowledge and experience are valid bases for expert opinions, *see, e.g., United States v. Ceballos*, 302 F.3d 679, 686 (7th Cir. 2002), and cannot be captured on a list.

Plaintiffs also cherry-pick a portion of Dr. Baertschi's testimony to argue that he did not use ***any*** methodology in forming his opinions, *see* Motion at 9—an assertion belied by his report and the broader context of his testimony. As Plaintiffs acknowledge, Dr. Baertschi later explained that his approach was not only more robust than what he described in the cherry-picked passage, but that it was the same methodology he has used during his scientific career:

> Q: Did you employ a methodology as an expert witness in this case?
>
> A: Yes. I mean, I was a little struck by the word and tried to figure out what that means. But the kind of methodology I use is the same analytical type of methodology I use for all my problem-solving in my career and for investigating things, and that is to read appropriate, relevant references, documents, experimental information, to collate, assemble that, to analyze it, to use logic, and to bring my knowledge and background to putting the pieces together and solving a problem. So it's the same kind of methodology I've used my entire career.
>
> Q: Is it the same methodology you've used in your career when approaching the preparation of peer-reviewed publications like those in your report?
>
> A: Yes, exact same kind of approach. We invest- -- reading as much as you can to learn the -- learn the subject and then piecing it together to create a new product -- an understanding to solve a problem.
>
> Q: Is it the same methodology you employed when you were working at Eli Lilly?
>
> A: Yes, it is the same.

Baertschi Dep. 282:6-283:7. He also testified about his method for selecting the case materials he reviewed in depth from among the voluminous documents available to him. *See id.* at 40:7-41:2. Plaintiffs cite no legal or scientific support for the claim

that reading and analyzing documents and assembling information "is not an objective scientific method" for an analytical chemist. Motion at 10. Indeed, courts have specifically recognized that reviewing scientific materials is a valid methodology where, as here, it is the methodology used in the field. *See, e.g.*, *Kannankeril*, 128 F.3d at 809 (allowing testimony where expert in part "relied on general experience and readings, general medical knowledge, standard textbooks, and standard references"); *Josephson v. Ganzel*, Case No. 3:19-cv-230, 2023 U.S. Dist. LEXIS 39624, at *37 (W.D. Ky. Mar. 8, 2023) (holding that expert's testimony "is the product of reliable principles and methods" where it "involve[d] no other scientific methodology aside from his own review, evaluation, and analysis based on his knowledge"); *Ad Astra Recovery Servs. v. Heath*, Case No. 18-1145, 2021 U.S. Dist. LEXIS 56438, at *16 (D. Kan. Mar. 5, 2021) ("Although Defendants have cited to several cases in an attempt to argue that [expert] has no methodology to arrive at his opinion, Defendants have not cited to any authority that would suggest accountants employ some other methodology other than reviewing financial and business records.").

In short, Plaintiffs have raised no real challenge to Dr. Baertschi's general methodology other than their unsupported claim that he was required to consider and opine on additional materials and subjects outside the scope of his report and

expertise. Their position has no legal or scientific underpinning and does not provide a basis for exclusion of Dr. Baertschi's opinions.

B. Dr. Baertschi employed a reliable methodology in opining that Teva acted as a reasonably careful and prudent manufacturer in making, inspecting, and testing its valsartan products.

In challenging Dr. Baertschi's specific opinions that Teva acted as a reasonably careful and prudent finished dose manufacturer in inspecting and testing its incoming valsartan API and manufacturing and testing its finished dose valsartan products, Plaintiffs largely rehash their general complaint that he did not consider matters outside the scope of his report and expertise. They start from the unsupported premise that Dr. Baertschi was required to "consider[] and apply[] the ***full scope of regulations, standards,*** current good manufacturing practices (cGMPs) and required standard operating procedures (SOPs) ***that govern Teva's conduct*** as a pharmaceutical finished dose manufacturer." Motion at 14 (emphasis added). They then assert—again without support—that he should have considered and opined on topics including Teva's regulatory compliance, including its compliance with cGMPs with no relevance to product manufacturing and testing, such as its qualification of ZHP as a supplier; Teva's quality agreements with ZHP; "the responsibilities between owners and contract suppliers"; and whether Teva's finished dose products met the regulatory definition of "adulterated." *See* Motion at 15-16. Having cited **no** authority, Plaintiffs baldly conclude that Dr. Baertschi

"cannot possibly" opine that "Teva acted as a 'reasonably prudent' and 'careful' finished dose pharmaceutical manufacturer" "without consideration of these mandatory regulations (such as the CFRs and cGMPs)." Motion at 16. But Dr. Baertschi is not opining on Teva's general conduct as a pharmaceutical company; his opinions are specific to its compliance with industry standards pertaining to the making, inspecting, and testing of products. *See* Baertschi Report ¶¶ 12-16.

Courts have specifically recognized that an expert opining on industry standards from a scientific perspective may not be an expert in regulatory standards, and vice versa. *See, e.g.*, *Crockett v. Luitpold Pharms., Inc.*, Case No. 19-276, 2023 U.S. Dist. LEXIS 28988, at *5–8 (E.D. Pa. Feb. 22, 2023) (noting that plaintiffs mischaracterized the scope of a medical expert's testimony as offering opinions about a drug label from a regulatory perspective, when in fact she offered them from a physician's perspective and holding that she was qualified to opine on labeling and warnings from that perspective); *Cline v. Boston Sci. Corp.*, Case No. 5:14-cv-5090, 2021 U.S. Dist. LEXIS 59112, at *18 (W.D. Ark. Mar. 29, 2021) (holding that analytical chemist was qualified to opine on "regulatory and industry standards for the design and manufacture of mesh products" but was not qualified to opine on "the FDA's particular testing and certification processes and standards, as he admittedly has no FDA-related training or experience"); *Bartoli v. Novartis Pharms. Corp.*, Case No. 3:13-cv-0724, 2014 U.S. Dist. LEXIS 52956, at *18 (M.D. Pa. Apr. 17,

2014) ("Dr. Parisian may testify as to the FDA regulatory scheme and the role of the FDA and its interactions with pharmaceutical companies" but may not testify about pharmaceutical industry ethical standards because "[t]here is nothing to suggest that she is an expert in pharmaceutical company ethics - she has never worked at a pharmaceutical company, and ethical standards for such companies do not come from the FDA…."). And Plaintiffs' organic chemist, Dr. Hecht, has opined on Defendants' compliance with industry standards while admitting that he is ***not "an expert in regulatory or FDA issues***" and has no experience with pharmaceutical regulation. *See* Hecht Dep. 35:12-16; 239:3-10. The Court should disregard Plaintiffs' unsupported argument that Dr. Baertschi (in contrast to Dr. Hecht, apparently) was required to opine on Teva's compliance with FDA regulations and ***any*** cGMPs applicable to a pharmaceutical manufacturer to offer reliable opinions on product manufacturing, inspecting, and testing.

Plaintiffs also contend that Dr. Baertschi's methodology was flawed because they disagree with his opinions on which industry standards are relevant to Teva's conduct in manufacturing and testing its valsartan products and the conclusions he draws from those standards—which is not a basis for the exclusion of expert opinions. *See, e.g.*, *Oddi*, 234 F.3d at 145-46; *see also Broe v. Manns*, Case No. 3:15-cv-985, 2016 U.S. Dist. LEXIS 167593, at *10 (M.D. Pa. Dec. 5, 2016) ("Any disagreement plaintiffs have with the expert can be dealt with through cross-

examination, presentation of contrary evidence and proper jury instructions."). Plaintiffs first suggest (without support) that Dr. Baertschi ***should not have relied on the USP Monograph for valsartan*** because it does not discuss NDMA or NDEA "as they are not an expected or accepted part of the approved formulation of valsartan." Motion at 17. Of course, Dr. Baertschi's opinion is that the Monographs "reveal the inability of compendial impurity methods to detect the low levels of NDMA or NDEA found in valsartan." Baertschi Report ¶ 34. He also opines that specialized equipment and analytical testing methods are needed to detect impurities at such low levels, which were not employed and had not been developed before Novartis's discovery of NDMA and NDEA because (as Plaintiffs recognize) the presence of nitrosamine impurities was unexpected. *See* Baertschi Report ¶¶ 13-14, 57, 59. Setting aside their baseless suggestion that Dr. Baertschi should not have relied on the valsartan Monograph at all, Plaintiffs do not contend that his opinion that compendial analytical methods, including those in the Monographs and ANDA, were unable to detect the presence of NDMA or NDEA is based on an unreliable methodology.

Plaintiffs next offer their own opinion that the NDMA and NDEA in valsartan do not fall under the "Other Impurities" section of the Monographs because they are "known to be toxic" and critique Dr. Baertschi for not addressing their unsupported belief in his report. *See* Motion at 17-18. But when Plaintiffs' counsel tested their

theory on Dr. Baertschi during his deposition, pointing out the language about substances "known to be toxic," he testified, "I'm not sure I understand the relevance. . . . By saying any substance known to be toxic, means you have to know the structure of that impurity." Baertschi Dep. 272:20-273:11. He then explained that "in order for you to have an analytical -- develop an analytical procedure for something that's unusually toxic, you have to know that you have an unusually toxic compound and what the structure is. You can't develop an analytical procedure for unknown entities that might be out there because that chemical space is -- is almost like infinity. It's way too large." *Id.* at 289:23-290:8. Plaintiffs may disagree with Dr. Baertschi's ***conclusions***, but that does not mean that his methodology was unreliable in his reliance on the Monographs generally or on the specific sections he understands to be applicable to Teva's analysis and testing of valsartan.

Plaintiffs again rely on only their disagreement with Dr. Baertschi's opinions in asserting that he failed to consider whether the USP General Requirements required the implementation of new testing capable of detecting NDMA and NDEA as a result of the process change. *See* Motion at 18-19. They note that that the USP General Requirements provide that nonmonograph testing should be employed "for detecting and controlling impurities that may result from a change in the processing methods" and assert that when asked about this at his deposition, Dr. Baertschi "reverted to the refrain that Teva did not know the impurity profile had changed as

a result of the new synthetic routes, so they didn't know to test for NDMA or NDEA." Motion at 18. In fact, Dr. Baertschi explained that the requirement is that the manufacturer perform a risk assessment to assess the potential for the formation of additional or different impurities as a result of the process change, which Teva and ZHP both did. *See* Baertschi Dep. 268:21-270:6. Far from ignoring this topic, Dr. Baertschi opines that the formation of NDMA and NDEA was unexpected and was not predicted by anyone in the industry, including the FDA, through analysis of the process change. *See* Baertschi Dep. 126:2-127:17, 151:9-16, 154:5-13. Dr. Baertschi thus had no reason to specifically opine on "whether the process change required the implementation of new nonmonograph testing suitable for detecting the NDMA and NDEA that could be formed as part of the process." *See* Motion at 18-19. There would be no basis for implementing new testing capable of detecting impurities that were not predicted to be present. Again, Plaintiffs disagree with Dr. Baertschi's conclusions, but they fail to show that he disregarded relevant evidence in reaching them. *See, e.g.*, *In re Fisher-Price Rock 'N Play Sleeper Mktg., Sales Pracs. & Prods. Liab. Litig.*, 567 F. Supp. 3d 406, 415 (W.D.N.Y. 2021) ("A difference in opinion is not a basis for exclusion of an expert opinion under *Daubert* standards.").

Plaintiffs acknowledge and gloss over Dr. Baertschi's reliance on relevant industry standards and cGMPs, including ICH Q3A and Q3B, M7, and other cGMPs

relevant to product manufacturing (which, they acknowledge, he testified are implicit in the standards he discusses in his report related to pharmaceutical manufacturing) in forming his opinions.[4] *See* Motion at 15, 19. They then assert that, nonetheless, "[i]t is impossible for Dr. Baertschi to render scientifically supported opinions on Teva's conduct, the propriety of Teva's reliance on ZHP's faulty analysis of its valsartan API or in Teva's own testing and risk assessment of the ZHP API, when he did not study the mandatory regulatory responsibilities Teva has as a pharmaceutical manufacturer."[5] *Id.* at 20. Yet, Dr. Hecht opines on Teva's analysis and testing of its valsartan products, while admitting that he is not familiar with the FDA's process for reviewing ANDAs and did not review Teva's ANDA, is not an expert in regulatory or FDA issues, has never evaluated any pharmaceutical manufacturer's compliance with cGMPs with respect to manufacturing practices for

[4] Plaintiffs oddly assert that ICH guidelines "do not support Dr. Baertschi's theory that NDMA and NDEA only require identification once they reach 0.1% of the API." Motion at 19 n.28. This characterization of Dr. Baertschi's opinions is both inaccurate and illogical. It is inaccurate because Dr. Baertschi clearly opined in his report and at his deposition that NDMA and NDEA are considered DNA reactive genotoxins, such that the lower identification thresholds under M7 would apply to them (if predicted to be present). *See* Baertschi Report ¶¶ 18-20; Baertschi Dep. 147:9-148:3. It is illogical because it starts from the presumption that NDMA and NDEA are present. Dr. Baertschi's opinion is that the presence of NDMA and NDEA in valsartan was unexpected. Therefore, as he repeatedly explained, the limits specified by ICH Q3A and 3B and M7 do not apply at all, because they deal with impurities expected to be present. *See, e.g.*, Baertschi Dep. 288:22-289:10.

[5] Plaintiffs also suggest Dr. Baertschi should have relied upon unspecified Watson/Actavis Standard Operating Procedures. Motion at 19. But they do not explain why, other than, again, their say-so.

pharmaceuticals, and reviewed only 13 Teva documents (none of which are SOPs) Hecht Dep. 35:12-16; 238:9-13; 260:4-261:6; 263:4-19. Plaintiffs again point to no case law or scientific explanation for why it was "impossible" for Dr. Baertschi to opine on these same subjects without consideration of Teva's "mandatory regulatory responsibilities … as a pharmaceutical manufacturer." Motion at 20. They have thus offered no cognizable basis for the exclusion of these opinions.

C. Dr. Baertschi employed a reliable methodology in rendering his opinion that Teva's finished dose product is "the same" as the Referenced Listed Drug.

Plaintiffs' challenge to Dr. Baertschi's methodology in opining that Teva's valsartan was the "same" as the Reference Listed Drug (RLD) can be swiftly discarded because it rests on a misunderstanding of his methodology. *See* Motion at 20-22. Contrary to Plaintiffs' belief, Dr. Baertschi ***does not rely on the USP Monographs*** in offering this opinion. *See* Baertschi Report ¶¶ 33-36. In fact, he opines that Teva's valsartan was the same as the RLD because the levels of all impurities were ***within the specification limits approved by the FDA via the ANDA***—a fact Plaintiffs' own expert, Philip Russ, concedes. *See* Baertschi Report ¶ 36; *see also* Deposition of Philip James Russ (January 5, 2023) ("Russ Dep.") at 168:23-169:14, 172:16-24 (excerpts attached to the accompanying Certification of Victoria Davis Lockard, Esq. as Exhibit B). Dr. Baertschi also explains that Plaintiffs' definition of the "same" as the RLD (i.e., "the 'chemical composition'

must be 'identical'") "would mean that every lot of a product produced, even by the same manufacturer, would qualify as a 'different' product, since variations in levels of impurities present, both above and below specification limits, are a reality allowed by the specifications that are approved by regulatory authorities; this is especially true if trace levels of impurities are included"—an opinion Plaintiffs' Motion ignores.[6] Baertschi Report ¶ 36. In short, Plaintiffs' challenge to Dr. Baertschi's methodology fails for the simple reason that it is unrelated to the methodology he actually used.[7]

For the same reason, the Court's exclusion of the opinions of Aurobindo's expert Dr. Jason Clevenger—which were based on the Monographs—is irrelevant to Dr. Baertschi's opinions and methodology. *See* Motion at 21-22. The Court excluded Dr. Clevenger's opinions ***on bioequivalence*** because "the basis for this was Dr. Clevenger's reading and interpretation of the compendial tests and acceptance criteria in United States Pharmacopeia ['USP'] monographs for

[6] Dr. Baerschi also explains that the NDMA and NDEA eventually detected in valsartan do not meet the definition of an "active ingredient" because they were "not ***intended*** to change the structure of the body." *See* Baertschi Report ¶ 37. Plaintiffs do not challenge or address this opinion either. *See* Motion at 20-22.

[7] Even though irrelevant to Dr. Baertschi's opinion that Teva's valsartan was the "same" as the RLD, it is ***Plaintiffs*** who use backward reasoning to assert—again—that Dr. Baertschi was required to consider the USP Monograph General Requirements on substances known to be toxic in rendering this opinion. Again, as Dr. Baertschi explained repeatedly, a substance must be identified before it can be determined to be toxic. *See, e.g.*, Baertschi Dep. 273:8-11 ("By saying any substance known to be toxic, means you have to know the structure of that impurity.").

valsartan. Having found that no valsartan USP monographs specifically dictate that valsartan API must be tested for nitrosamine impurities, Dr. Clevenger concluded the absence of any mention of nitrosamines in valsartan USP monographs must mean logically that the VCDs at issue are the same as the identical compendial standard of 'identity, strength, quality, and purity' of the RLD." *See* Class Certification Opinion ("Class Opinion") (Feb. 8, 2023) at 76. Dr. Baertschi does not rely on the Monographs in rendering his opinion on Teva's valsartan's "sameness" to the RLD, so the Court's conclusions as to Dr. Clevenger are inapplicable.[8]

Plaintiffs' challenge to Dr. Baertschi's opinions that Teva's valsartan was the "same" as the RLD is based only on a misunderstanding of his methodology and should be denied.

D. Dr. Baertschi does not directly opine on ZHP's risk assessment, and Plaintiffs provide no cognizable basis for preclusion of his opinion that the formation of NDMA and NDEA was unexpected and not predicted or his opinions related to Teva's risk assessment.

Plaintiffs seek to preclude "any opinion" from Dr. Baertschi on ZHP's risk assessment of the process change—a topic on which he does not directly opine in his Report. *See* Motion at 22; *see generally* Baertschi Report. Plaintiffs' counsel,

[8] Dr. Clevenger opined on bioequivalence and concluded "[t]here is 'no evidence that therate / extent of contaminated valsartan differs from that of the reference listed drug," and therefore valsartan batches containing nitrosamines were bioequivalent to the RLD. *See* Class Opinion at 76. Dr. Baertschi does not opine on bioequivalence. *See* Baertschi Report ¶¶ 33-36.

though, inquired during his deposition whether ***Dr. Baertschi*** had done a chemical risk assessment and now apparently seek to preclude his responses to that line of questioning. *See* Baertschi Dep. 125:16-126:1. In response to this questioning, Dr. Baertschi responded that after hearing of the recall in 2018, he and his peers performed an assessment of the synthetic process change and openly wondered whether or not they would have caught the potential for the formation of nitrosamines. *See id.* at 125:21-127:17. Nowhere in the testimony Plaintiffs challenge does Dr. Baertschi opine on the chemical risk assessment that ZHP undertook in connection with the process change. *See id.* Instead, his testimony supports his opinion that the formation of NDMA and NDEA was not predicted by anyone in the industry. *See id.* at 126:13-127:17. To the extent Plaintiffs are challenging Dr. Baertschi's characterization of the formation of NDMA and NDEA as unexpected, the basis for that opinion is thoroughly explained in Dr. Baertschi's report and testimony, *see, e.g.*, Baertschi Report ¶¶ 53-55; Baertschi Dep. 151:9-16, 154:5-13, 291:18-24, 292:9-293:7, 293:22-295:14, and Plaintiffs' Motion provides no basis to preclude it.

Plaintiffs' argument related to Dr. Baertschi supposedly not knowing that a Teva entity manufactured valsartan API (never sold in the United States) is both inaccurate and irrelevant to his opinions. *See* Motion at 23-24. As an initial matter, Dr. Baertschi's deposition correction sheet clarifies that he "had forgotten that Teva

had a subsidiary that manufactured valsartan API at one point; [but that it] does not impact my opinions in this case." *See* Errata Sheet to the January 26, 2023, Deposition Transcript of Steven Baertschi, Ph.D. (attached to the accompanying Certification of Victoria Davis Lockard, Esq. as Exhibit C). And again, Dr. Baertschi testified repeatedly that ***no*** manufacturer or regulatory agency caught the potential for the formation of NDMA and NDEA when analyzing ZHP's process change. *See, e.g.,* Baertschi Dep. 151:9-16, 154:5-13, 288:7-21, 291:18-24, 292:9-293:7, 293:22-295:14. This included API manufacturers. In any case, as discussed more below, Dr. Baertschi does not opine on whether Teva "could have" or "should have" detected the potential for the formation of valsartan through its risk assessment. *See generally* Baertschi Report. Nor has he evaluated or opined on Teva's "qualification of an API supplier"—notwithstanding that Plaintiffs would have liked him to do so. *See* Motion at 24.

Almost as an afterthought, Plaintiffs challenge Dr. Baertschi's opinions related to ***Teva's*** risk assessment of ZHP's process change—again couching their disagreement with his conclusions as a failure to consider relevant evidence. *See* Motion at 24-25. As an initial matter, Dr. Baertschi's opinion is that Teva "followed the relevant and appropriate processes in connection with the process change," "which included analysis reflecting that tested lots of valsartan made from the 'proposed process' met all specifications," as well as a risk assessment. Baertschi

Report ¶¶ 39-40. He also notes that the conclusion of the risk assessment was that the proposed change "imposes no risk on the manufacturing process of Valsartan or Valsartan HCT"—a fact, not an opinion he needed to support with analysis. *See id.* ¶ 40; Motion at 24. Plaintiffs raise no challenge to the actual opinions Dr. Baertschi offers in his report related to Teva's risk assessment. *See id.*

Plaintiffs' challenge to what they characterize as Dr. Baertschi's opinions on Teva's risk assessment is really just an argument supporting their view of the case, with little to do with Baertschi's opinions. *See* Motion at 24-26. Notably, Plaintiffs never identify the specific supposed opinions by Dr. Baertschi to which their argument relates. *See id.* Instead, they suggest that he should have conceded that Teva should have foreseen the potential for the formation of NDMA and NDEA through its chemical risk assessment. *Id.* But, again, Dr. Baertschi's opinion is that the presence of NDMA and NDEA was unexpected, and he amply explains the basis for that opinion, including "the fact that ZHP and none of the other finished-dose manufacturers, in their assessments, predicted it or viewed it as expected, they didn't discover it and they didn't predict it as a reasonably likely impurity, nor did two very reputable -- at least two regulatory agencies, EMA and FDA. So based on the fact that all those competent organizations and -- and regulatory agencies did -- view it as an unexpected, that they, even in hindsight, they continue to refer to it as an unexpected finding, that validates the idea that it's not reasonably expected."

Baertschi Dep. 288:7-21. He also explained why Plaintiffs' argument about the supposed obviousness of the potential for the formation of NDMA and NDEA through a chemical risk assessment is an inappropriate lens through which to view the risk assessments at the time they were performed:

> A. Even though with the benefit of hindsight people -- people can declare that it's very predictable because the chemistry can be explained, that's different than -- than when you're looking at without the benefit of that knowledge.
>
> Q. Without the retrospective.
>
> A. Without the hindsight, without the retrospective.

Baertschi Dep. 293:2-10. Plaintiffs' ability to prove their case hinges on a different conclusion, but that is irrelevant to whether the opinions Dr. Baertschi has actually offered stem from a reliable methodology. *See, e.g.*, *Oddi*, 234 F.3d at 145-46. Plaintiffs can argue their view of the case to the jury in closing arguments.

E. Dr. Baertschi employed a reliable methodology in reaching his opinions on Teva's residual solvents testing.

In challenging Dr. Baertschi's opinions about Teva's residual solvents testing, Plaintiffs repeat their refrain that he should have considered additional evidence supporting Plaintiffs' view of the case, ignoring Dr. Baertschi's explanations about why he did not consider it. *See* Motion at 26-28. They start from the demonstrably untrue premise that "***[i]t is undisputed*** that Novartis, a finished drug product manufacturer like Teva, seeking to purchase ZHP valsartan API discovered the presence of nitrosamines when conducting routine residual solvent gas

chromatography testing because the chromatograms had unknown peaks," citing the report of their expert, Dr. Najafi. Motion at 26 (emphasis added). But Dr. Baertschi testified that after reviewing all information available regarding why Novartis was conducting the testing that ultimately detected NDMA, "I am uncertain, unclear as to why they really were doing that investigation." Baertschi Dep. 33:1-10. He further explained, "[t]he context, what was the motivation for them to be looking at the residual solvents. I am not confident I understand what that motivation was." *Id.* at 33:12-19. In fact, ***Plaintiffs' own expert***, Dr. Hecht, disagrees with Dr. Najafi's opinion that Novartis discovered NDMA during "routine residual solvents gas chromatography testing." He testified:

> [I]n order to find NDMA in the testing, you need to be looking for it. All right? The peaks -- the NDMA peak would be too small for it to stand out. That's why some of these companies missed it, because they looked at the solvents, the ones we were just talking about. They're going to be like relatively larger peaks. The NDMA peak is going to be very small. So you wouldn't see it. You wouldn't notice it unless you were actually looking for it.

Hecht Dep. 203:15-24. Whatever Plaintiffs' challenges to Dr. Baertschi's opinion that it was "reasonable and appropriate for a finished dose manufacturer like Teva not to perform further analysis of unidentified peaks of the size seen on Teva's chromatograms of valsartan API batches that were ultimately determined to be NDMA / NDEA," *see* Baertschi Report ¶¶ 16, 45-55, Dr. Hecht apparently agrees with it.

Plaintiffs next assert that Dr. Baertschi failed to consider "contradictory evidence" because he did not address the FDA's findings of cGMP violations in a warning letter to ZHP sent ***after the identification of NDMA by Novartis***. Motion at 27-28. Again, Dr. Baertschi was not asked to opine on ZHP's testing or conduct. But when shown the warning letter during his deposition, he opined that:

> [I]t's telling that [the FDA] said 'you may have found indicators of – of NDMA.' My -- as I look at the chromatograms that I was able to look at, it looks to me like it's logical that – it's logical to see that they would not have found it unless they were specifically doing something different. And the something different is sample prep and chromatography…. To say that you may have found it is what happened with Novartis because they did different approaches to the residual solvent analysis. They used different methodology.

Baertschi Dep. 239:21-240:23. He further testified, "[Dr.] Hecht agreed that you wouldn't discover it unless you were looking for it. So I don't think it's controversial for me to say I do not believe that they would have identified it just by looking at those small peaks, because there were other peaks larger than the NDMA, and you're looking for indicators of residual solvents likely to be present." *Id.* at 241:23-242:9. Plaintiffs do not explain why Dr. Baertschi was required to specifically cite the FDA's warning letter to ZHP to reliably render an opinion with which their own expert agrees, based on his review of the same chromatograms. *See* Motion at 28.

In their final jab at Dr. Baertschi's methodology, Plaintiffs complain that he only reviewed the tabulated results of Teva's residual solvents testing, baldly declaring that "[r]eview of tabulated results cannot possibly be a sound basis to opine

on the appropriateness of failing to evaluate unidentified peaks….” Motion at 28-29. In addition to being entirely unsupported, this argument ignores Dr. Baertschi’s testimony that “[w]ith regard to the actual solvents that they were reporting, you would not need to look at the chromatogram to assess that.” Baertschi Dep. 138:5-11. He went on to explain that having reviewed ZHP’s chromatograms, he did not need to look at Teva’s because “you can see from the ZHP testing where they used the validated method, which is analogous to the method that would be used at Teva.” *Id.* at 139:10-20. Plaintiffs overlook these explanations and instead discuss an irrelevant case involving customer service data presented to an expert in the form of a histogram. Motion at 29. They do not explain why this scenario—despite facially sounding “similar”—has any applicability to Dr. Baertschi’s review of the tabulated results of Teva’s testing and of his reliance on ZHP chromatograms resulting from an analogous methodology.

Ultimately, in arguing that Dr. Baertschi supposedly failed to consider “contradictory” evidence, Plaintiffs do not bother to address his explanations as to why he did not consider or did not need to consider it. Dr. Baertschi explained the “good grounds” supporting his methodology and the materials on which he relied in opining on Teva’s residual solvents testing. *See, e.g., In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d at 792–93. Any disagreement Plaintiffs

have with his methodology can be addressed through cross examination. *See, e.g., Broe*, 2016 U.S. Dist. LEXIS 167593, at *10.

CONCLUSION

For all these reasons, Teva respectfully requests the Court deny Plaintiffs' Motion to Preclude the Opinions of Defendants' Expert Steven W. Baertschi.

Dated: April 11, 2023

Respectfully Submitted:

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CERTIFICATE OF SERVICE

I hereby certify that on April 11, 2023, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

By: */s/ Steven M. Harkins*
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